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08/235,241 04/29/94 FREUDENBERG

W	5552.1164020
EXAMINER	

TOUZEAU, L

ART UNIT	PAPER NUMBER
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12

18M2/0613
FINNEGAN, HENDERSON, FARABOW, GARRETT
AND DUNNER
1300 I STREET, N. W.
WASHINGTON, DC 20005-3315

1811
DATE MAILED: 06/13/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 4-29-94 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-12 are pending in the application.
Of the above, claims — are withdrawn from consideration.
2. ☒ Claims 8 have been cancelled.
3. ☐ Claims — are allowed.
4. ☒ Claims 1-7 + 9-12 are rejected.
5. ☐ Claims — are objected to.
6. ☐ Claims — are subject to restriction or election requirement.
7. ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on —. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on —, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed —, has been ☐ approved; ☐ disapproved (see explanation).
12. ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. 867410; filed on 4/7/92.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

15. The rejection of claims 1,2,3,5,6,7,9, 10 and 12 made under 35 USC 102(a) in paper No. 8 issued from this Office 11/1/93 has been withdrawn. The rejection of claims 1,2,3,5,6,7,9,10 and 12 made under 35 USC 102(e) in paper No. 8 has been withdrawn. The rejection of claims 1-7 and 9-12 made under 35 USC 103 in paper No. 8 has been withdrawn.

16. The use of trademarks such as POLYSORBATE 20 (page 3, line 27) and TWEEN (page 5, line 31) have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to teach adequately how to make and/or use the invention. Applicant has not disclosed any and all polymers: he has only disclosed how to use sucrose. While Applicant discloses a factor VIII:C activity of at least 1000 IU/mg, the specification teaches it is possible to prepare, without teaching how it is to be accomplished, factor VIII:C activity of more than 2000 IU/mg (page 4, line 3) or more than 5000 IU/mg (page 5, lines 24-25). Claim 1 is not commensurate in

scope with the enablement.

18. Claims 1-7 and 9-12 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification. The scope of claim 1 is too broad as it reads on and encompasses any amino acid or any one of its salts or any of its homologs or any detergent or any organic polymer in any permutation of combinations. It is an open invitation to experiment. The terms "an amino acid (claims 1, 12) "salts" and "homolog(s)" (claims 1, 7, 12), and "buffering substances" (claim 7) are too broad as they encompass too wide a variety of species. for the reasons set forth in the objection to the specification in paragraph 17, above.

19. Claims 1-7 and 9-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1, 7 and 12, the term homolog is indefinite the term may refer to naturally occurring or synthetic derivatives which may or may not have been discovered. In claims 1 and 12, the terms amino acids," "one of its salts," "detergent," and "organic polymer" are indefinite as each of these agents has not been clearly, concisely and exactly specified.

~~THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.~~

~~A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.~~

Any inquiry concerning this communication should be directed to
P. Lynn Touzeau, Ph.D at telephone number (703) 308-0196.

PLT 1 *PT* June 1994

HOWARD E. SCHAIN
SENIOR LEVEL EXAMINER
GROUP 1800

Howard E. Schain